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CONNETICS CORPORATION and CONNETICS AUSTRALIA PTY. LTD., Plaintiffs, v. AGIS INDUSTRIES (1983) LTD., Defendant.	05 Civ. 05-5038 (HAA) **REDACTED PUBLIC VERSION**

BRIEF IN SUPPORT OF DEFENDANT'S RULE 56 MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT

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I. INTRODUCTION.

Agis is entitled to summary judgment of non-infringement. While this case presents straightforward and simple issues, Connetics undoubtedly will work hard trying to convince this Court otherwise. Connetics has no choice, of course, but to employ such tactics – Connetics needs to keep this case alive because its existence is the only reason that Agis has been unable to bring consumers an affordable generic version of Connetics' Olux® brand drug product. Indeed, but for Connetics' baseless infringement allegations, Agis would have been able to begin marketing its generic product over a year ago, when FDA completed its review of Agis' application and deemed it ready for approval.

The claims of Connetics' patent spell out in unambiguous detail the numerous required elements. No direct literal infringement of this method patent can be found unless each and every one of those elements is found in Agis' generic product. While a single missing element is sufficient to entitle Agis to summary judgment, the fact is that several of the required patent claim elements are missing.

Similarly, while Connetics certainly will try, it cannot prevail on its claim that the use of Agis' formulation infringes under the doctrine of equivalents. The inventors' statements to the Patent Office during the prosecution of the patent-in-suit estop Connetics from asserting a claim under the doctrine of equivalents against Agis. Indeed, even if Connetics could assert infringement under the

doctrine of equivalents, it still cannot prevail here because its equivalents argument fails as a matter of law. Specifically, the only way Connetics can muster an equivalents argument is by completely ignoring certain elements of the asserted claims. But the Federal Circuit does not allow Connetics to vitiate claim terms, and thus its arguments fail under the "all-limitations" rule.

In the end, Connetics has deprived consumers of an affordable generic product long enough. Agis is entitled to judgment in its favor.

II. BACKGROUND.

A. Hatch-Waxman Amendments.

This action arises under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"). *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984). Congress enacted Hatch-Waxman for the express purpose of "get[ting] generic drugs into the hands of patients at reasonable prices – fast." *In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

A company seeking FDA approval to sell a new drug must file a new drug application ("NDA") with complete studies of safety and efficacy. *See* 21 U.S.C. § 355(b)(1). An NDA also must contain the number and expiration date of any patent that claims "the drug" or a method of using "the drug" for which the application was submitted. *Id.* §§ 355(b)(1), (c)(2). The FDA publishes this information in what commonly is known as the "Orange Book."

A company seeking FDA approval to market a generic version of an NDA drug files an abbreviated new drug application ("ANDA"). Rather than repeating the NDA-holder's safety and efficacy studies, the ANDA applicant demonstrates that its product is "bioequivalent" to the brand product. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); 21 U.S.C. § 355(j).

An ANDA applicant seeking FDA approval to market a generic drug before expiration of a patent appearing in FDA's Orange Book must submit a so-called "paragraph IV certification" stating that such patent is invalid and/or will not be infringed by the ANDA product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). By submitting a paragraph IV certification, the applicant commits "a highly artificial act of [patent] infringement." *Eli Lilly*, 496 U.S. at 678; 35 U.S.C. § 271(e)(2). That is, Hatch-Waxman contains a jurisdictional mechanism allowing for patent infringement actions *before* the ANDA drug actually has been marketed. Consequently, the focus in cases like this one is on "what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248 (Fed. Cir. 2000). Where, as here, the ANDA seeks approval to market a well-defined drug, "the ultimate question of infringement is usually straightforward." *Id.* at 1249.

If the brand company files an infringement suit after receiving notice of the paragraph IV ANDA submission, that suit – regardless of merit – automatically

stays final FDA approval of the ANDA for up to 30 months unless the court finds non-infringement and/or invalidity earlier. *See* 21 U.S.C. § 355(j)(5)(B)(iii). As a result, brand companies like Connetics have a strong financial incentive to bring an infringement action. In this case, not only did doing so allow Connetics to maintain its monopoly far longer than permissible, but it also gave Connetics time to launch a "next generation" product that will deprive Agis and consumers of the cost savings that flow from generic market entry.

B. Factual Background.

1. Procedural Background.

In 2005, Agis filed ANDA No. 77-763 with the FDA seeking approval to market a generic version of Connetics' Olux® branded product. (SOF ¶ 5).[1] Olux®, which is a topical foam used to treat skin disease, contains the corticosteroid clobetasol propionate, 0.05%, as the active ingredient. (SOF ¶ 4). Because Connetics listed U.S. Patent No. 6,126,920 ("the '920 patent") in the FDA's Orange Book in connection with Olux®, Agis' ANDA contains a paragraph IV certification, stating that the '920 patent is invalid or will not be infringed. (SOF ¶ 9). As required by statute, Agis sent Connetics notice of this paragraph IV ANDA submission. (SOF ¶ 10).

[1] "SOF" refers to the 56.1 Statement of Undisputed Facts; "Ex. __" refers to an exhibit attached to the Declaration of Melissa E. Flax; "Chambliss Dec." refers to the Declaration of Walter G. Chambliss; and "Baldwin Dec." refers to the Declaration of Steven W. Baldwin, submitted herewith in support of Agis' motion.

After Connetics received the notice, Agis provided a copy of its ANDA and several samples of its ANDA products. Nevertheless, in an effort to delay competition, Connetics filed an infringement suit against Agis on October 19, 2005. (SOF ¶ 11). By filing suit, Connetics prevented FDA from finally approving Agis' product for 30 months, unless this Court enters a finding of non-infringement sooner. That 30-month stay ends in March 2008.

After nearly two years of litigation, Connetics finally identified the asserted claims of the '920 patent – claims 1-6 and 8-12. (SOF ¶¶ 12-13). Not even Connetics could come up with a basis for asserting literal infringement of claim 4, instead asserting infringement under the doctrine of equivalents only. (SOF ¶ 13). Agis steadfastly denies infringement. (SOF ¶ 15).

2. The '920 Patent.

The '920 patent contains 15 method claims, all directed to administering a pharmaceutical composition to a patient for the treatment of skin disease. Independent claims 1 and 4 read as follows:

> 1. *A method* of treating a skin disease susceptible to treatment with corticosteroid active substances, said method comprising administering topically to a patient in need thereof, an effective amount of a foamable *pharmaceutical composition comprising* a corticosteroid active substance, a quick-break foaming agent that comprises an aliphatic alcohol, water, a fatty alcohol and a surface active agent; *a propellant*; and *a buffering agent present in an amount sufficient to provide a pH within the range of 3.0 to 6.0.*

> 4. *A method* of treating a skin disease susceptible to treatment with corticosteroid active substances, said method comprising administering topically to a patient in need thereof an effective amount of a foamable *pharmaceutical composition comprised of* a quick-break foaming agent that comprises an aliphatic alcohol, water, a fatty alcohol and a surface active agent *a propellant*; an active isomer of an isomeric corticosteroid active substance; and *an amount of a buffering agent effective to stabilize the active isomer against isomerization to a less active isomer.*

(SOF ¶ 40 (emphasis added)). All remaining claims depend from claim 1 and thus incorporate all limitations of claim 1. *See* 35 U.S.C. § 112, ¶ 4. Consequently, every claim requires the presence of a "buffering agent."

The specification emphasizes that including a "buffering agent" is critical to the claimed invention, and shows what the inventors meant by the term "buffering agent." The specification states, for example:

> In view of the complexity of the composition, it has been found that unexpectedly in order to ensure stability of the active isomer of the corticosteroid in the composition and thus to ensure delivery of the most active isomer to the epidermis, *it is necessary to buffer the composition by including a suitable buffering agent. Suitable buffering agents are acetic acid/sodium acetate, citric acid/sodium citrate, an and phosphoric acid/sodium phosphate,* and it is desirable generally to buffer the composition to pH 3.0-6.0, preferably 4.0 – 5.0 . . . It is *particularly preferred to use a citrate buffer system more preferably anhydrous citric acid/potassium citrate . . . .*

(SOF ¶ 45).

3. Agis' Clobetasol Propionate ANDA Product.

Agis' proposed generic clobetasol propionate foam composition contains the following ingredients, which perform the function listed below:

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REDACTED

REDACTED

FDA tentatively approved Agis' ANDA on August 30, 2006. (SOF ¶ 96). Agis has not received final approval because of this lawsuit.

III. ARGUMENT.

A. AGIS IS ENTITLED TO JUDGMENT IN ITS FAVOR.

There are no material facts in dispute: Connetics has not and cannot come forth with evidence sufficient to establish infringement either literally or under the

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doctrine of equivalents. Agis thus is entitled to judgment of non-infringement as a matter of law.

1. Summary Judgment Standard.

A grant of summary judgment is appropriate where, as here, "there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Wolverine World Wide, Inc., v. Nike, Inc.*, 38 F.3d 1192, 1196 (Fed. Cir. 1994); *Sule v. Kloehn Co.*, 149 F. Supp. 2d 115, 118 (D.N.J. 2001) (Ackerman, J.). The party seeking summary judgment has the burden of production, which may be met "either by demonstrating that there is no genuine issue of fact and that the moving party must prevail as a matter of law, or by demonstrating that the nonmoving party has not produced sufficient evidence relating to an essential element of the case for which it bears the burden of proof." *Sule*, 149 F. Supp. 2d at 118-119. Once either showing is made, the nonmoving party "must demonstrate facts supporting each element for which it bears the burden, as well as establish the existence of a genuine issue of material fact." *Id.* at 119. "[I]f the non-movant's evidence on any essential element of the claims asserted is merely colorable or is not significantly probative, the court should enter summary judgment in favor of the moving party." *Weiss v. The Prudential Ins. Co.*, 497 F. Supp. 2d 606, 609 (D.N.J. 2007) (Ackerman, J.).

Here, there is no issue of material fact, and Connetics has not produced (and cannot produce) the requisite evidence for a finding of infringement. In response to this motion, Connetics will present nothing more than a series of circular, convoluted infringement theories. Connetics hopes that it can obscure reality enough to make it to trial because even a loss at trial months from now is a "win" for Connetics – it means Connetics continued to successfully delay the introduction of generic competition.

Connetics' circular theories begin with the unsupported assumption that the use of Agis' product must infringe. For example, in Connetics' litigation view,

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And while Agis has no affirmative legal obligation to come forward with evidence proving this, it has done so, and has done so convincingly and without material contradiction. Agis is entitled to judgment in its favor.

2. This Court Can Decide The Issues In This Case On Summary Judgment.

Summary judgment is appropriate here, where resolution of Agis' motion concerns questions of law and no genuine issues of material fact. First, "claim

construction is a question of law amenable to summary judgment; a mere dispute over the meaning of a term does not itself create an issue of fact." *Wolverine World Wide*, 38 F.3d at 1196. Second, "[i]f any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Bayer*, 212 F.3d at 1247.

Agis has come forth with clear evidence that use of its ANDA product does not literally infringe the '920 patent. Connetics has not, and cannot, come up with any disputes on facts material to that issue. Where, as here, the material facts regarding the accused product are not in dispute, "the question of literal infringement collapses into claim construction and is amenable to summary judgment." *Gen. Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 983 (Fed. Cir. 1997); *see also K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1362 (Fed. Cir. 1999).

Similarly, Connetics has not, and cannot, come up with any disputes on facts material to infringement under the document of equivalents. As an initial matter, "whether prosecution history estoppel applies, and hence whether the doctrine of equivalents may be available for a particular claim limitation, presents a question of law." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1367 (Fed. Cir. 2003). In this case, Connetics is estopped from applying the doctrine of equivalents to key claim limitations. Even if the Court allowed Connetics to invoke the doctrine of equivalents, it would not help Connetics. Use

of Agis' ANDA product does not infringe under the doctrine of equivalents under the Federal Circuit's "all limitations" rule, which holds that "an element of an accused product or process is not, as a matter of law, equivalent to a limitation of the claimed invention if such a finding would entirely vitiate the limitation." *Freedman Seating Co. v. American Seating Co.*, 420 F.3d 1350, 1358 (Fed. Cir. 2005). Because Connetics' theory of infringement under the doctrine of equivalents necessarily would vitiate key elements of the claims, there can be no infringement under the doctrine of equivalents as a matter of law.

B. CLAIM CONSTRUCTION.

Determining whether a patent claim is infringed is a two-step inquiry, the first of which requires the Court to construe the claims to determine their "scope and meaning." *Wolverine World Wide*, 38 F.3d at 1196. Doing so requires the Court to look "to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1315-17, 1324 (Fed. Cir. 2005) (en banc) (same). Typically, as in this case, "analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term." *Vitronics*, 90 F.3d at 1583.

The relevant claim terms in need of construction are: "buffering agent" (all asserted claims) and "to provide a pH within the range of 3.0 to 6.0" (claim 1 and

all dependent claims). According to the intrinsic evidence of record, and consistent with its ordinary meaning, the term "buffering agent" is properly construed as a separate component that consists of a weak acid and its conjugate salt. Likewise, the intrinsic evidence shows that the claim term "to provide a pH within the range of 3.0 to 6.0" means to maintain the pH of the composition within the range of 3.0 to 6.0. Because "buffering agent" appears in every claim, construing that term in accordance with its plain meaning, and with the way the inventors use that term, entitles Agis to judgment in its favor regardless of how the Court construes the other term.[3]

1. "Buffering Agent".

a. The '920 Patent Claims.

Each claim in the '920 patent requires the pharmaceutical composition to contain a "buffering agent" as an ingredient separate and apart from the other ingredients. The claims themselves make plain that the term "buffering agent" means a separate component of the pharmaceutical composition that consists of a weak acid and its conjugate salt (sometimes referred to as its conjugate base).

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[3] As discussed *infra*, Agis also is entitled to judgment in its favor on all claims because REDACTED This term, however, does not require the Court's construction. Similarly, because the clobetasol propionate in Agis' ANDA formulation REDACTED , Agis does not infringe that claim. But this term does not require the Court's construction.

Claim 1 requires, among other things, "a foamable *pharmaceutical composition comprising* a corticosteroid active substance, a quick-break foaming agent that comprises an aliphatic alcohol, water, a fatty alcohol and a surface active agent; a propellant; *and a buffering agent* . . . ." (SOF ¶ 40 (emphasis added)). Claim 4 similarly requires a "foamable *pharmaceutical composition comprised of* a quick-break foaming agent that comprises an aliphatic alcohol, water, a fatty alcohol and a surface active agent a propellant; an active isomer of an isomeric corticosteroid active substance; *and an amount of a buffering agent* . . . ." (SOF ¶ 40 (emphasis added); *see also* Chambliss Dec. ¶ 36; Ex. 17 at 30-32, 37 (Plaintiffs' expert testifies that one of the required ingredients listed in claim 1 is a "buffering agent")).

Unasserted claims 13 and 15 underscore that the required "buffering agent" is an independent component, separate and apart from the other required ingredients in the pharmaceutical composition:

> 13. The method according to claim 1, further characterized in that *the buffering agent is selected from the group consisting of a citrate buffer, an acetic acid/sodium acetate buffer and a phosphoric acid/sodium phosphate buffer.*

15. The method according to claim 1, further characterized in that the foamable pharmaceutical composition comprises:

	% w/w
Betamethasone Valerate	0.120
Cetyl Alcohol BP	1.100
Octadecan-1-ol BP	0.500
Polysorbate 60 BP	0.400
Ethanol	57.790
Purified Water	33.690
Propylene Glycol BP	2.000
Citric Acid Anhydrous BP	*0.073*
Potassium Citrate	*0.027*
Butane/Propane	4.300
	100.000.

(SOF ¶ 40 (emphasis added)).

These claims also underscore that the patentees used the term "buffering agent" consistent with its plain meaning to a person of skill in the art, *i.e.*, that a "buffering agent" is the combination of a weak acid and its conjugate base. Indeed, Connetics does not dispute that all of the specifically claimed "buffering agents" are combinations of a weak acid and its conjugate salt. (SOF ¶ 43). The fact that these two dependent claims require the "buffering agent" to be a separate component consisting of specific weak acid/conjugate salt pairs reinforces that the term "buffering agent" must be construed as a separate component that consists of a weak acid and its conjugate salt. *See Phillips*, 415 F.3d at 1314-15.

b. The '920 Patent Specification.

The specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315; *SciMed Life Systems, Inc. v. Advance Cardiovascular Sys.*, 242 F.3d 1337, 1344-45 (Fed. Cir. 2001) (holding that the written description of the invention found in the specification "can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format" and limiting claims in light of the specification); *Bell Atl. Network Servs. v. Covad Commc'ns. Group*, 262 F.3d 1258, 1268 (Fed. Cir. 2001) ("the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents").

AstraZeneca AB v. Mutual Pharmaceutical Co., 384 F.3d 1333 (Fed. Cir. 2004), is analogous to the situation presented here. In that case, the court limited the claim term "solubilizer" in a pharmaceutical patent to "surfactants" based upon statements in the specification that described "the suitable solubilizers" as surfactants; the fact that every one of the preferred solubilizers listed in the specification was a surfactant; and the fact that in each of the examples in the specification, the preferred solubilizer was a surfactant. *See id.* at 1339-41.

Here, the '920 patent specification makes clear that the term "buffering agent" means a separate component of the composition that consists of a weak acid and its conjugate salt. The specification describes both suitable and preferred buffering agents, all of which are combinations of a weak acid and its conjugate salt: "Suitable buffering agents are acetic acid/sodium acetate, citric acid/sodium citrate and phosphoric acid/sodium phosphate . . . . It is particularly preferred to use a citrate buffer system, more preferably anhydrous citric acid/potassium citrate . . . ." (SOF ¶ 45). Moreover, the specification contains only one example of the claimed pharmaceutical composition, and it contains citric acid anhydrous BP/potassium citrate as the buffering agent, which is a weak acid and its conjugate salt. (SOF ¶ 48). Finally, all of the "buffering agents" described in the specification are comprised of a weak acid and its conjugate salt. (SOF ¶ 46 (Plaintiffs' expert testifies the only buffering agents listed in the specification are weak acid/ conjugate salt pairs)).

Thus, as in *Astrazeneca*, the '920 patent inventors made clear, through the statements and examples in their specification that they meant the term "buffering agent" to be limited to a combination of two separate ingredients; namely, a weak acid and its conjugate salt.

c. The Prosecution History Of The '920 Patent.

The prosecution history is "often of critical significance in determining the meaning of the claims." *Vitronics*, 90 F.3d at 1582. It "provides evidence of how the PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317. Indeed, "[a]rguments and amendments made during the prosecution of a patent application and other aspects of the prosecution history . . . must be examined to determine the meaning of terms in the claims." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995); *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319, 1325 (Fed. Cir. 2002) (same).

A reading of the prosecution history, in fact, often allows a court to determine "whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317. That is, "[t]he prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." *Southwall*, 54 F.3d at 1576; *Rheox*, 276 F.3d at 1325 (same). Thus, statements the inventors made distinguishing the claimed invention from the prior art are instructive as to what the claims do not encompass. *See Vitronics*, 90 F.3d at 1583 ("Included within an analysis of the file history may be an examination of the prior art cited therein."); *Autogiro Co. v. U.S.*, 384 F.2d 391, 399 (Ct. Cl. 1967) ("[T]he prior art cited in the file wrapper gives clues as to what the claims do not cover.").

Here, the patentees made several arguments contrasting the alleged invention of the '920 patent with the prior art. Specifically, during prosecution, the inventors repeatedly emphasized that a composition of the '920 patent must contain a "buffering agent," and unambiguously disclaimed prior art compositions that the inventors stated did not contain a "buffering agent."

The patent examiner rejected the claims of the '920 method patent as obvious over two prior art references, European Patent Application 0 484 530 A1 ("EPA") and published PCT application WO 85/01876 ("WO"). (SOF ¶ 53). EPA discloses compositions containing active ingredients (including corticosteroids) and inactive ingredients such as aliphatic alcohol, water, fatty alcohol, surface active agents, propellants, and a glycol (such as propylene glycol). (SOF ¶ 57). WO discloses foam compositions containing active ingredients and inactive ingredients such as aliphatic alcohol, water, fatty alcohol, surface active agents, emollients (such as propylene glycol), propellants, and, optionally, organic acid salts. (SOF ¶ 56).

In response to the examiner's rejection, the '920 inventors emphasized that their invention, unlike the pharmaceutical compositions described in EPA and WO, requires the addition of a "buffering agent":

> [I]t is one aspect of the present invention to overcome the problems of instability of corticosteroids in liquid compositions. The present inventors have discovered that the stability of such preparations may be improved by controlling the acidity of the composition and *the*

> *claims thus require the presence of a buffering agent* to maintain the pH of the composition within the range of 3 to 6. . . . . EPA provides no teaching or suggestion that the stability of corticosteroids in liquid compositions may be improved by controlling the acidity of the composition and *there is clearly no teaching that would motivate the person of skill to include a buffering agent* to maintain the pH of the composition within the range of 3 to 6. *This teaching is only provided by Applicants' disclosure.*
>
> With regard to WO, this reference describes a biocidal composition that includes a quick-break foaming agent. The Examiner states that it would have been obvious to replace the biocidal agent with the steroid of EPA and thus achieve Applicants' claimed corticosteroid-containing quick-break foam composition . . . . *because neither reference provides any disclosure with respect to controlling the pH of the composition between 3 and 6, neither reference can be said to provide any motivation to alter the other in the ways necessary to achieve Applicants' claimed compositions.*
>
> Moreover, while the compositions of EPA and WO may or may not be analogous, even if as asserted by the Examiner, one were motivated to replace the biocidal agent of WO with the steroid of EPA, the claimed invention would not be achieved. *Applicants' compositions require the presence of a buffering agent to maintain the pH within the range of 3 to 6. This is a requirement neither taught nor even recognized by either of EPA or WO.*

(SOF ¶¶ 54-55 (emphasis added)).[4]

The fact is, the inventors had no choice but to distinguish their alleged invention from the prior art relied on by the examiner based upon the criticality of a "buffering agent" being present in the '920 compositions. Prior art

[4] As is evident from this passage, and as discussed *infra*, the inventors not only emphasized the criticality of the "buffering agent," but also emphasized the requirement to maintain the pH within the specific range of 3.0 to 6.0. (SOF ¶¶ 54, 55, 60).

compositions, including those at issue during prosecution, contained everything found in the compositions in the '920 patent except a "buffering agent":

'920 Patent	WO	EPA	EP 331,489 A2	Woodford et al.
corticosteroid active substance		X		X
aliphatic alcohol	X	X	X	X
water	X	X	X	X
fatty alcohol	X	X	X	X
surface active agent	X	X	X	X
propellant	X	X	X	X
buffering agent				

(SOF ¶ 58).[5]

Connetics cannot simply walk away from the inventors' unequivocal statements or the content of the prior art. *See, e.g., Gillespie v. Dywidag Sys. Int'l, USA*, -- F.3d --, No. 2006-1382, 2007 WL 2493339, at *4-5 (Fed. Cir. Sept. 6, 2007) (stating that "[t]he patentee is held to what he declares during the prosecution of his patent" and holding that claim construction could not encompass features in prior art that were distinguished in arguments to examiner, regardless of whether they were material to grant of patent) (Ex. 32).

Connetics will, of course, try to avoid the prosecution history. Indeed, it has no choice. Connetics will ask this Court to construe "buffering agent" to mean one

[5] EP 331,489 A2 and *Woodford et al.* were not before the examiner during the '920 prosecution. This Court, of course, has the discretion to consider such art, and doing so can be helpful during claim construction. *See In re Cortright*, 165 F.3d 1353, 1358 (Fed. Cir. 1999).

or more substances that achieve and maintain pH when added to a solution. The Court cannot so construe this term. For one, such a construction would eliminate the sole difference that the inventors said existed between the claimed invention and the prior art, as shown above. And, of course, Connetics "may not proffer an interpretation for the purposes of litigation that would alter the indisputable public record consisting of the claims, the specification and the prosecution history, and treat the claims as a 'nose of wax.'" *Southwall*, 54 F.3d at 1576 ("[c]laims may not be construed one way in order to obtain their allowance and in a different way against accused infringers."); *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003) ("A patentee may not state during prosecution that the claims do not cover a particular device and then change position and later sue a party who makes that same device for infringement.").

The file history confirms what the language of the claims and the specification already tells the reader: when the inventors used the term "buffering agent," they meant a separate component of the pharmaceutical composition that consists of a weak acid and its conjugate salt.

2. "To provide a pH within the range of 3.0 to 6.0".

a. The '920 Patent Claims.

Claim 1 (and all the asserted dependent claims) requires a pharmaceutical composition containing "a buffering agent present in an amount to provide a pH

within the range of 3.0 to 6.0." A plain reading of the claims makes clear that the pH range specified is precise. The inventors did not use broadening words, such as "approximately" or "about," nor did they quantify an amount above or below this range that the patent should cover. As the Federal Circuit has held, "[w]ithout broadening words that ordinarily receive some leeway, the precise [pH] range[] of claim 1 do[es] not avoid a strict numerical boundary to the specified parameter." *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1381 (Fed. Cir. 2000). Thus, the claims do not cover pHs that fail to stay within the range of 3.0 to 6.0.

b. The '920 Patent Specification.

Consistent with the claims, the specification refers to the pH range of the claimed composition only in precise terms: "it is desirable generally to buffer the composition to pH 3.0-6.0, preferably 4.0-5.0." (SOF ¶ 47). Again, the inventors clearly contemplated that the pH of any claimed composition would stay within the precise range of 3.0-6.0. This is further confirmed by the fact that the preferred pH range falls squarely within the 3.0-6.0 range, as well as the fact that the specification does not even mention a pH above 6.0 or below 3.0.

c. The Prosecution History Of The '920 Patent.

As set forth above, the inventors repeatedly represented that the compositions of the '920 patent "require the presence of a buffering agent *to maintain the pH within the range of 3 to 6.*" (SOF ¶¶ 54 - 55) (emphasis added)).

In doing so, the inventors made clear that not only must the pH of the claimed composition *fall within* the range of 3.0 to 6.0, but that it must be *maintained* within that range. From these repeated remarks to the examiner, the inventors plainly did not intend to claim a formulation that, for example, had a pH that was 5.8 one day and 6.8 the next, because that composition does not maintain a pH within the 3.0 to 6.0 range. Again, "[t]he patentee is held to what he declares during the prosecution of his patent." *Gillespie*, 2007 WL 2493339, at *5.

3. Even If Connetics Could Use Extrinsic Evidence, It Would Not Help Its Claim Construction.

Where, as here, a review of the intrinsic evidence "resolve[s] any ambiguity in the disputed claim term . . . it is improper to rely on extrinsic evidence." *Vitronics*, 90 F.3d at 1583. And in no circumstance may extrinsic evidence be used "to arrive at a claim construction that is at odds with the intrinsic evidence." *Playtex Prods. v. Procter & Gamble Co.*, 400 F.3d 901, 908 & n.1 (Fed. Cir. 2005) (holding that the "district court erred in relying upon extrinsic evidence that directly contradicted" the intrinsic evidence); *see also Vitronics*, 90 F.3d at 1583 (holding that extrinsic evidence may not be used to change the intrinsic evidence).

In this case, Connetics' extrinsic evidence cannot properly be considered by this Court. First, resort to any extrinsic evidence is improper here because the intrinsic evidence unambiguously defines the relevant claim terms. Second, resort to Connetics' extrinsic evidence in particular is improper because Connetics'

experts tried to adopt a definition of "buffering agent" entirely inconsistent with, and that contradicts, the intrinsic evidence – both how the inventors use the term in the patent and prosecution history, and with published literature in the relevant art giving the ordinary meaning of this term. While Connetics had no choice but to try this tactic, the law does not allow it. Thus, even if this Court were to look at extrinsic evidence, the only such evidence that lawfully could be considered are the opinions expressed by Agis' experts because they are consistent with the intrinsic evidence and relevant published literature. (*See* Exs. 3, 5, 8; *see also* Ex. 7).

C. USE OF AGIS' ANDA PRODUCT DOES NOT DIRECTLY INFRINGE THE '920 PATENT.

Every single one of the claims of the '920 patent is directed to a "method" for treating a skin disease with a pharmaceutical composition, "said method comprising administering [the composition] topically to a patient in need thereof . . . ." (SOF ¶¶ 39-41). As a pharmaceutical company, Agis does not and will not administer its proposed ANDA product to patients. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 & n.7 (Fed. Cir. 2003). Consequently, any direct infringement would take place at the patient level, forcing Connetics to demonstrate that Agis somehow is indirectly infringing the asserted claims. But without direct infringement, there can be no indirect infringement. *See Joy Techs. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed. Cir. 1993). And, in this case, there is no direct infringement of the '920 method patent.

1. Use Of Agis' ANDA Product Does Not Literally Infringe.

Administering Agis' ANDA product does not literally infringe any of the claims of the '920 patent

REDACTED

Connetics, of course, does not even argue that the ANDA product literally infringes claim 4. (SOF ¶¶ 13-14).

"Literal infringement requires that the accused device embody every element of the claim." *Builders Concrete, Inc. v. Bremerton Concrete Prods. Co.*, 757 F.2d 255, 257 (Fed. Cir. 1985). "The patentee bears the burden of proving infringement by a preponderance of the evidence" and the "failure to meet a single limitation is sufficient to negate infringement of [a] claim." *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991). In Hatch-Waxman cases, the infringement inquiry involves an examination of the product the applicant will likely market if

approved. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). Where, as here, the ANDA "is to sell [a] well-defined compound," then the "ultimate question of infringement is usually straightforward." *Id.*

a. Agis' ANDA Composition REDACTED

Every claim of the '920 patent requires a "buffering agent."

REDACTED

REDACTED

b. Agis' ANDA Composition REDACTED

REDACTED

As properly construed, claim 1 (and its dependent claims) claim a pharmaceutical composition containing a "buffering agent" present in an amount "to maintain the pH of the composition within the range of 3.0 to

6.0." That is, to infringe claim 1, the pH of the composition must contain a "buffering agent" *and* have a pH that remains within the range of 3.0 to 6.0.

REDACTED

c. Agis' ANDA Composition REDACTED

REDACTED

REDACTED

2. The Use Of Agis' ANDA Product Does Not Infringe The Asserted Claims Under The Doctrine Of Equivalents.

Prosecution history estoppel prevents Connetics from asserting that the use of Agis' product infringes the '920 patent under the doctrine of equivalents. Even if Connetics could assert a claim under the doctrine of equivalents, Agis' ANDA product does not infringe under the all limitations rule, *i.e.*, the Federal Circuit rule precluding Connetics from reading claim limitations out of the asserted claims.

a. Prosecution History Estoppel Prevents Connetics From Asserting Infringement Under the Doctrine Of Equivalents.

Prosecution history estoppel "limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during the prosecution of the patent." *Southwall*, 54 F.3d at 1579. A patentee's arguments to

the PTO create an estoppel. *See Laitram Corp. v. Morehouse Indus.*, 143 F.3d. 1456, 1464 (Fed. Cir. 1998). This is true regardless of whether those arguments were necessary to distinguish the patentee's invention over the prior art, or were necessary for the allowance of a claim. *Id.*; *Southwall*, 54 F.3d at 1583 ("Clear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim" will create an estoppel.). Thus, "the limits imposed by prosecution history estoppel on the permissible range of equivalents can be broader than those imposed by the prior art." *Southwall*, 54 F.3d at 1581.

REDACTED

As previously discussed at length, the patent examiner rejected the claims as being unpatentable over the prior art references EPA and WO. (SOF ¶ 53). In response, the patentees repeatedly and unmistakably told the PTO that the compositions of the '920 patent "*require the presence of a buffering agent* to maintain the pH within the range of 3 to 6" and that "[t]his is a requirement neither taught nor even recognized by either of EPA or WO." (SOF ¶ 54 - 55 (emphasis added)). The applicants also told the examiner that if one were to "replace the biocidal agent [*i.e.*, the active ingredient] of WO with the steroid of EPA, the claimed invention would *not* be achieved." (SOF ¶ 55 (emphasis added)).

REDACTED

Thus, the use of Agis' ANDA composition cannot infringe under the doctrine of equivalents in light of the inventors' clear and unmistakable representations to the PTO. *Morehouse*, 143 F.3d at 1464; *Southwall*, 54 F.3d at 1583; *Marquip, Inc. v. Fosber Am., Inc.*, 198 F.3d 1363, 1367 (Fed. Cir. 2000) (doctrine of equivalents cannot be applied to ensnare prior art).

b. Connetics Cannot Vitiate Claim Elements When Arguing That Agis' Product Infringes Under The Doctrine Of Equivalents.

Even if prosecution history estoppel did not preclude Connetics from asserting that the use of Agis' ANDA composition infringes under the doctrine of equivalents, Agis' composition would still not infringe the claims of the '920

patent. Connetics, in asserting that Agis' composition infringes the claims of the '920 patent under the doctrine of equivalents, violates the "all limitations rule."

The "all limitations rule" holds that "an accused product or process is not infringing unless it contains each limitation of the claim, either literally, or by an equivalent." *Freedman*, 420 F.3d at 1358. With respect to the doctrine of equivalents, this rule "requires that equivalence be assessed on a limitation-by-limitation basis, as opposed to from the perspective of the invention as a whole." *Id.* In fact, "an element of an accused product or process is not, as a matter of law, equivalent to a limitation of the claimed invention if such a finding would entirely vitiate the limitation." *Id.*; *Lockheed Martin Corp. v. Space Sys./Loral*, 324 F.3d 1308, 1321 (Fed. Cir. 2003) (same). Courts must consider the totality of the circumstances in determining whether "the alleged equivalent can be fairly characterized as an insubstantial change from the claimed subject matter without rendering the pertinent limitation meaningless." *Freedman*, 420 F.3d at 1359.

i. Connetics Impermissibly Reads The Term "Buffering Agent" Out Of The Claims.

REDACTED

REDACTED

Connetics' assertion impermissibly reads the "buffering agent" limitation out of the claims.

REDACTED

"a foamable pharmaceutical composition comprising a corticosteroid active substance, a quick-break foaming agent that comprises an aliphatic alcohol, water, a fatty alcohol and a surface active agent; a propellant; *and a buffering agent* . . . ." (SOF ¶ 40 (emphasis added)).

REDACTED

Moreover, Connetics' theory does not compare Agis' composition to the asserted claims "on a limitation-by-limitation basis," but instead impermissibly focuses on the stability of the composition as a whole (including the pH). *Id.*

REDACTED

Connetics' "invention as a whole" argument of convenience ignores science, evidence, and

common sense. It also runs afoul of Federal Circuit law, which precludes such an analysis. Connetics' theory of infringement under the doctrine of equivalents must fail.

ii. Connetics Vitiates the Claim Element "Against Isomerization To A Less Active Isomer".

In addition to the reasons set forth above, Agis does not infringe claim 4 of the '920 patent under the doctrine of equivalents for another reason: Connetics' infringement theory completely reads out the claim limitation "against isomerization to a less active isomer."

REDACTED

The fact is, claim 4 specifically identifies the precise kind of degradation the buffering agent is supposed to prevent: isomerization to a less active isomer. If the words "against isomerization to a less active isomer" were read out of claim 4, Connetics might be able to argue that the claim could read on any type of

stabilization of the active isomer through the use of a buffering agent. (SOF ¶ 40). This exactly is how Connetics must read this claim in order to have an infringement allegation. But doing so would improperly vitiate the claim limitation "against isomerization to a less active isomer." Connetics' position is completely impermissible under the all limitations rule. Thus, Connetics' assertions that Agis' ANDA formulation infringes claim 4 under the doctrine of equivalents fail.

D. CONNETICS HAS NOT COME FORWARD WITH ANY EVIDENCE REGARDING INDIRECT INFRINGEMENT.

Connects apparently failed to realize until the very last minute that the '920 patent is a method patent. Its experts, for example, focused solely on direct infringement, omitting entirely from their opening reports any discussion of whether Agis indirectly infringes under 35 U.S.C. § 271(b) or (c). Connetics made a weak stab at concocting some type of indirect infringement theory in one of its rebuttal expert reports, but only after Agis' experts pointed out the lack of evidence on indirect infringement. Connetics' attempt fails as a matter of law. Connetics has not and cannot come forward with any evidence creating a dispute as to a material fact on this issue. Thus, even if Connetics could establish direct infringement by others (which it cannot), its claim still fails as a matter of law.

To prevail on contributory infringement under § 271(c), Connetics must prove, *inter alia*, that the Agis ANDA composition has no substantial non-

infringing uses (*i.e.*, it may not be used in non-infringing methods) and that Agis *knew* the composition was especially made or "adapted for use in an infringement of [the '920] patent." 35 U.S.C. § 271(c); *see also Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964) (stating the § 271(c) requires a showing that the alleged contributory infringer "knew that the combination for which his component was especially designed was both patented and infringing"); *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed. Cir. 2004) (same).

With respect to inducement, "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). This requires Connetics to prove that Agis knowingly induced another to commit an infringing act, *i.e.*, Agis actively and knowingly aids and abets another's direct infringement. The Federal Circuit has held that "the intent requirement for inducement requires more than just intent to cause the acts that produce direct infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006). Rather, Connetics must prove that Agis has an affirmative intent to cause direct infringement. *See id.*; *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 (Fed. Cir. 2005) (holding inducement requires that "the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement."); *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*,

545 U.S. 913, 936-37 (2005); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990).

REDACTED

But the law requires Connetics to prove more than that Agis intended to cause the acts that could produce direct infringement. *See BMC Res., Inc. v. Paymentech, L.P.*, No. 2006-1503, slip op. at 12 (Fed. Cir. Sept. 20, 2007) ("[I]ndirect liability requires evidence of 'specific intent' to induce infringement. Another form of indirect infringement, contributory infringement under § 271(c), also requires a *mens rea* (knowledge) and is limited to sales of components or materials without substantial noninfringing uses.") (Ex. 33); *see also DSU Med.*, 471 F.3d at 1306; *Aro Mfg.*, 377 U.S. at 488; *Golden Blount*, 365 F.3d at 1061. Connetics has no evidence showing that Agis "possessed specific intent to encourage another's infringement" or that Agis "knew" the composition was especially made or adapted for use in infringing the '920 patent.

Connetics lacks any evidence regarding the specific intent needed to sustain a claim for indirect infringement. Consequently, even if Connetics could raise a

genuine issue of material fact with respect to direct infringement (which it cannot), its indirect infringement claim against Agis still fails as a matter of law.

IV. CONCLUSION.

For the reasons set forth above, Agis is entitled to judgment of non-infringement of the '920 method patent as a matter of law. Connetics has failed to provide evidence of direct infringement either literally or under the doctrine of equivalents. Connetics also has failed to come forward with any evidence to support an indirect infringement claim against Agis.

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